

AMENDMENT TO THE CLAIMS:

The following claim set replaces all prior versions, and listings, of claims in the application:

1. (currently amended) A powdered formulation which is a freeze-dried mixture of a sensitive active material and an excipient ~~consisting of~~ comprising:
from 0.01 to 50 % by wt of the sensitive active material,
from 50 to 99.99 % by wt of the excipient,
~~from 0.1 to 10% by wt of additive/stabilizer,~~
wherein from 0.1 to 50 % by wt of the mixture is in an amorphous state sufficient to achieve a stable crystalline/amorphous matrix and obtain a reduced hygroscopicity of the formulation of less than 5% by weight after 8 hours in a 75% relative humidity environment;
wherein where the excipient is crystalline, it is selected from the group consisting of a eutectic salt, glycine, mannitol and sorbitol;
wherein where the excipient is amorphous, it is selected from the group consisting of glutamine, serine, a monosaccharide, a disaccharide, a trisaccharide, a polysaccharide, polyethylene glycols having a molecular weight of about 6000, a polyamino acid, poly-d-lactic acid, amorphous lactose, a polyethylene glycol having a molecular weight up to 1000, a polyglycan, a polysaccharide, a cyclodextrin, povidone, micro-fine cellulose, potato starch and a protein.
2. (previously presented) A formulation according to claim 1, of from 1 to 50 % by wt of the freeze-dried mixture in an amorphous state.
3. (previously presented) A formulation according to claim 1, comprising:
from 0.01 to 50 % by wt of sensitive active material in an amorphous state,
from 50 to 99.99% by wt of excipient in crystalline state,

- 0 - 5 % by wt of excipient in an amorphous state.
4. (previously presented) A formulation according to claim 1, comprising:
from 0.01 to 50 % by wt of sensitive active material in a crystalline state,
from 50 to 99.89% by wt of excipient in crystalline state, and
0.1 - 5 % by wt of excipient in an amorphous state.
 5. (previously presented) A formulation according to claim 1, comprising:
from 0.01 to 25 % by wt of an amorphous or a crystalline state of sensitive active
material,
from 75 to 99.49 % by wt of a crystalline state excipient, and
0.5 - 5 % by wt of excipient in an amorphous state.
 6. (previously presented) A formulation according to claim 1 in which a saccharide
is used to provide an excipient in an amorphous state.
 7. (previously presented) A formulation according to claim 1 in which a sugar
alcohol is used to provide an excipient in a crystalline state.
 8. (previously presented) A formulation according to claim 1 wherein the
formulation additionally comprises from 0.1 to 10% by wt of additive/stabilizer.
 9. (previously presented) A formulation as defined in claim 8 wherein the
additive/stabilizer is an antioxidant, a free radical scavenger and/or a Maillard
reaction suppresser.
 10. (previously presented) A formulation according to claim 1 wherein the sensitive
active material is a labile organic and/or inorganic molecule, a biopolymer, a
polypeptide, protein, enzyme, hormone, vitamin, antibiotic, polysaccharide, lipid,
killed or live whole live cell.

11. (previously presented) A formulation according to claim 10 wherein the sensitive active material is a virus (including phage), bacterium, fungus and/or eukaryote.
12. (canceled)
13. (canceled)
14. (canceled)
15. (previously presented) A dosage form comprising a formulation according to claim 1.
16. (previously presented) A dosage form according to claim 15 which is a container which comprises the formulation or an article which has been formed from the formulation.
- 17.-25. (canceled)
26. (previously presented) A powdered formulation which is a shelf freeze-dried mixture of a sensitive active material and an excipient comprising:
from 0.01 to 50 % by wt of the sensitive active material,
from 50 to 99.99 % by wt of the excipient,
wherein at least 0.1 % by wt of the mixture is in an amorphous state sufficient to achieve a stable crystalline/amorphous matrix and obtain a reduced hygroscopicity of the formulation of less than 5% by weight after 8 hours in a 75% relative humidity environment.
27. (previously presented) A formulation according to claim 1, wherein the formulation comprises from 0.1 to 50% by weight of the sensitive active material.
28. (previously presented) A formulation according to claim 1, wherein the formulation comprises from 0.5 to 50% by weight of the sensitive active material.

ADAMS et al
Serial No. 10/591,369
November 19, 2010

29. (previously presented) A formulation according to claim 1, wherein the formulation comprises from 50 to 99.9% by weight of the excipient.
30. (previously presented) A formulation according to claim 1, wherein the formulation comprises from 50 to 99.5% by weight of the excipient.